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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,879	01/16/2007	Steven Streatfield Gill	3174.00019	5420

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EXAMINER
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YANG, ANDREW

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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10/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/577,879	Applicant(s) GILL, STEVEN S.	
	Examiner Andrew Yang	Art Unit 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 21, 23-26 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

Claims 21, 23, 24, 25, 26 and 29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 21, 23, 24, 25, 26 and 29 have not been further treated on the merits.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 10, and 13 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter.

In claim 9, lines 2-3, applicant positively recites part of a human, i.e. "the edge of each plate that is inserted into the intervertebral gap".

In claim 13, lines 3-4, applicant positively recites part of a human, i.e. "the apical edge will engage with the anterior non-interstitial surfaces of the vertebrae"

Thus claims 9, 10, and 13 and include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive

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property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, lines 2-4, "the edge," "the posterior edge," and "the anterior edge" lack prior antecedents.

In claims 13, lines 2-3, "its flat bases" and "the posteriorly facing apical edge" lack prior antecedents.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

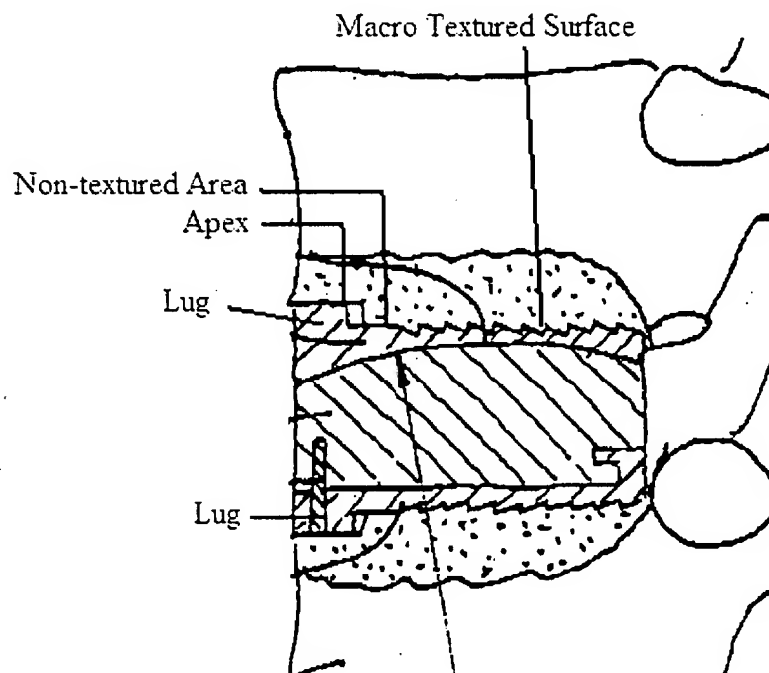
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-4, 7, 9, 11-14, 17-19, 26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Link (U.S. Publication No. 2005/0085911).

Link discloses an intervertebral prosthesis with a first plate 11 and a second plate 12. The plates are articulated together (Paragraph 9) and each has a substantially flat bone engaging surface with a macro textured surface and a lug that abuts a non-interstitial surface of the vertebrae upon insertion (See Figure Below). The macro-textured surface is also considered to be disc shaped since the implant as a whole is substantially disc shaped, therefore the surface of the plates 11, 12 are also disc shaped.



The implant does not have any fixing means or holes for receiving fixing means. Each plate 11, 12 also has non-textured area between the macro textured surface and the lug as seen in the figure above. With further reference to the figure above the lug is

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positioned on one side of each plate 11, 12. The lug is positioned on the anterior edge of each plate. The lugs are also considered capable of engaging an insertion tool. The lugs are prism shaped, since a prism is defined as a solid have bases that are parallel, congruent polygons and sides that are parallelograms (dictionary.com). As seen in the figure on the previous page the lug has a top surface and a bottom surface in the form of rectangles, and the sides are in the form of parallelograms. The flat base of the lug faces anteriorly and the posterior apical edge will engage a non-interstitial surface of the vertebrae.

With regard to claims 17-19, it is considered that the device as discloses is capable of being used as a trial device since all structural limitations have been disclosed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 8, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Link (U.S. Publication No. 2005/0085911).

Link discloses the claimed invention except for the non-textured area to be about .4-1mm lower than the macro textured surface and also the non-textured area forming a border between the macro textured surface and the lugs having a width between 2 and

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10mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the non textured surface to be about .4-1mm lower than the macro-textured surface and also the non-textured area forming a border between the macro textured surface that is between 2 and 10mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Link does not disclose that each plate has two lugs. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Link having two lugs on each plate, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Furthermore, Link discloses pits in the macro-textured surface between each apex of the macro-textured surface as seen in the figure previously presented. Link however, fails to disclose the pits have a radius of greater than .4mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the pits of Link with a radius of generally greater than .4 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Link also fails to disclose the implant being made of stainless steel, titanium, titanium carbide, zirconium or any biocompatible equivalent. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Link made from stainless steel, titanium, titanium carbide, zirconium or any biocompatible equivalent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Link (U.S. Publication No. 2005/0085911) in view of Foley (U.S. Publication No. 2004/0078079).

Link discloses the claimed invention except for the trial device formed as a single unit with an elongated handle. Foley teaches a trial instrument set 50 having a number of trial instruments 52, 54, 56, 58, 60, 62, etc. (Figure 5). Each instrument has a handle, a haft, and a trial body formed as one unit. The trial bodies have the same size and shape as an implant 40 for permanent implantation. The trial set is provided so that a desired disc space height can be determined so that a proper implant can be selected (Paragraph 6). It would have been obvious to one skilled in the art at the time the invention was made to provide the device of Link with a trial device with a trial body that is identical to a corresponding permanent implant and also formed as a single unit with a handle in view of Foley so that the height of the desired disc space could be determined and a proper implant could be selected.



Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Link (U.S. Publication No. 2005/0085911) in view of Carignan et al. (U.S. Patent No. 6319257).

Link discloses the claimed invention except for the insertion tool as claimed. Carignan et al. teaches an insertion tool having a shaft 18 and a cylinder 16. The shaft 18 has a distal end with two prosthesis engaging arms 34, 34' and a proximal end with a grip 14. The cylinder 16 is in rotational engagement with the shaft 18 (Column 6, Lines 9-13). The distal end of the cylinder 24 contacts the prosthesis engaging arms 34, 34' (Figure 9). Rotating the grip 14 causes the shaft 18 to be drawn into the cylinder 16 and causes the prosthesis engaging arms 34, 34' to be drawn together (Column 6, Lines 9-13). It is considered that holding the grip 14 and rotating the cylinder will have the same effect, since the drawing together of the arms is an effect of one member, the shaft 18, moving relative to another member, the cylinder 16. It would have been obvious to one skilled in the art at the time the invention was made to insert the device of Link with the insertion tool as claimed in view of Carignan et al. since Carignan et al. teaches a known technique and device for the purposes of inserting an implant into an intervertebral space which would have been known to one with ordinary skill in the art.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Link (U.S. Publication No. 2005/0085911) in view of Urbahns et al. (U.S. Patent No. 6264657).

Link discloses the claimed invention except for removing the implant by passing a chisel or osteotome between the macro-textured surface and each end plate of the vertebra. Urbahns et al. teaches removing an implant by passing an osteotome between the surface of the implant and each end plate of the vertebrae (Column 4, Lines 17-25). This procedure is done for removing devices during disc replacement surgery (Column 2, Lines 11-20). It would have been obvious to one skilled in the art at the time the invention was made to remove the device of Link with an osteotome in view of Urbahns et al. in order to remove the implant during disc replacement surgery.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached on 8:00am-5:30pm: Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.Y.

10/15/2007



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